



SEP 29 2005

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Ms. Bunny Abraham
295 Central Park West #3A
New York, New York 10024-3021

Re: Docket Number 2004P-0452/CP 1

Dear Ms. Abraham:

This letter responds to your citizen petition dated October 6, 2004, requesting that the Food and Drug Administration (FDA) require expiration dates on food products. You contend that some canned foods you have purchased were outdated and contained oil which was rancid. You contend that these products were still available on the market because there was no expiration date listed on the package. You further contend that "there is no reason for manufacturers to use codes on their products except to fool the public into buying a product even if it passes the expiration date."

In accordance with Title 21 of the Code of Federal Regulations (CFR) 10.30(e)(3), this letter is to advise you that FDA is denying your petition, without prejudice.

As evidenced by the exhibits attached to your petition, some manufacturers use "codes" on their labels. These codes, which might appear on canned or boxed foods, are usually understood only by the manufacturer and others in the industry. Manufacturers may use these codes to track inventory, rotate stock, or locate a product under suspicion of a problem. However, these codes do not indicate safety, freshness or quality of a product, and are not the same as expiration dates.

Regarding your request that FDA require expiration dates on all food products, FDA has only limited regulatory authority to require expiration dates on food products under FDA's oversight. For example, to implement the Infant Formula Act of 1980, FDA has required expiration dating "use by" dates on infant formula to inform retailers and consumers that the infant formula, until that declared date, will contain the quantity of each nutrient as specified on the label and that the formula is otherwise of an acceptable quality (see 21 CFR 107.20 (c) (copy enclosed)). Please note that this "use by" date on infant formula does not relate to food safety. While there may be circumstances that would warrant the agency requiring expiration dates on other foods regulated by FDA, you did not submit any data or other information that provides a basis for FDA to require expiration dates on particular food products.

FDA encourages and supports the voluntary use of expiration date labeling on foods, and some foods, such as cereals, are voluntarily labeled with expiration dates. It is our understanding that dates printed voluntarily on such food packages refer to the quality, rather than the safety, of the product.

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In addition, some State and local agencies require expiration date labeling, for example, on perishable dairy, bakery, and egg products. The agency notes, however, that a food may spoil before its labeled expiration date, if, for example, it is stored under improper conditions.

For the reasons stated above, FDA is denying your petition.

Sincerely yours,

Margaret O’K. Glavin
Senior Associate Commissioner
for Regulatory Affairs

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2004]
[CITE: 21CFR107.20]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

PART 107 -- INFANT FORMULA

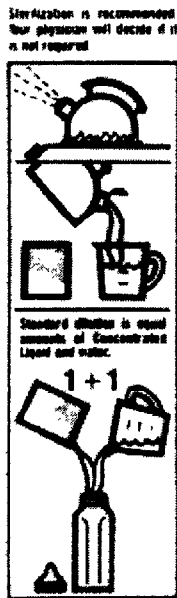
Subpart B -- Labeling

Sec. 107.20 Directions for use.

In addition to the applicable labeling requirements in parts 101 and 105 of this chapter, the product label shall bear:

(a) Under the heading "Directions For Preparation and Use", directions for:

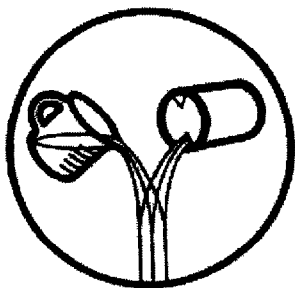
- (1) Storage of infant formula before and after the container has been opened, including a statement indicating that prolonged storage at excessive temperatures should be avoided;
 - (2) Agitating liquid infant formula before opening the container, such as "Shake Well Before Opening";
 - (3) "Sterilization" of water, bottle, and nipples when necessary for preparing infant formula for use;
 - (4) Dilution of infant formula, when appropriate. Directions for powdered infant formula shall contain the weight and volume of powdered formula to be reconstituted.
- (b) In close proximity to the "Directions for Preparation and Use" a pictogram depicting the major steps for preparation of that infant formula, such as (for a concentrated formula):



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(c) A "Use by ____" date, the blank to be filled in with the month and year selected by the manufacturer, packer, or distributor of the infant formula on the basis of tests or other information showing that the infant formula, until that date, under the conditions of handling, storage, preparation, and use prescribed by label directions, will: (1) when consumed, contain not less than the quantity of each nutrient, as set forth on its label; and (2) otherwise be of an acceptable quality (e.g., pass through an ordinary bottle nipple).

(d) The statement "Add Water" or "Do Not Add Water", as appropriate, to appear on the principal display panel of concentrated or ready-to-feed infant formulas. In close proximity to the statement "Add Water", a symbol such as



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if the addition of water is necessary. The symbol shall be placed on a white background encircled by a dark border.

(e) A warning statement beneath or in close proximity to the "Directions For Preparation and Use" that cautions against improper preparation or use of an infant formula, such as "THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE".

(f) A statement indicating that parents should consult their physicians about the use of infant formulas, such as "USE AS DIRECTED BY A PHYSICIAN".

[50 FR 1840, Jan. 14, 1985, as amended at 67 FR 9585, Mar. 4, 2002]